

Patent Claims

- 1) Pharmaceutical composition, characterised in that it contains one or more tiotropium salts (1) combined with one or more salmeterol salts (2), optionally in the form of the enantiomers, mixtures of enantiomers or in the form of the racemates thereof, optionally in the form of the solvates or hydrates and optionally together with a pharmaceutically acceptable carrier.
- 2) Pharmaceutical composition according to claim 1, characterised in that the active substances 1 and 2 are contained either together in a single preparation or in two separate preparations.
- 3) Pharmaceutical composition according to one of claims 1 or 2, characterised in that 1 is contained in the form of the chloride, bromide, iodide, methanesulphonate, para-toluenesulphonate or methylsulphate, preferably in the form of the bromide.
- 4) Pharmaceutical composition according to one of claims 1 to 3, characterised in that 2 is selected from the salts of hydrochloric acid, hydrobromic acid, sulphuric acid, phosphoric acid, methanesulphonic acid, acetic acid, fumaric acid, succinic acid, lactic acid, citric acid, xinafonic acid or maleic acid, with the proviso that 2 cannot denote salmeterol xinafoate if 1 denotes tiotropium bromide.
- 5) Pharmaceutical composition according to claim 4, characterised in that 2 is selected from the salts hydrochloride, hydrobromide, sulphate, phosphate and methanesulphonate, preferably from hydrochloride and sulphate.
- 6) Pharmaceutical composition according to one of claims 1 to 5, characterised in that the ratios by weight of tiotropium 1' to salmeterol 2' are in a range from 1:300 to 30:1, preferably from 1:230 to 20:1.
- 7) Pharmaceutical composition according to one of claims 1 to 6, characterised in that a single administration corresponds to a dosage of the active substance combination 1' and 2' of from 0.01 to 1000 µg, preferably from 0.1 to 200 µg.

- 8) Pharmaceutical composition according to one of claims 1 to 7, characterised in that it is in the form of a preparation suitable for inhalation.
- 9) Pharmaceutical composition according to claim 8, characterised in that it is a preparation selected from among the inhalable powders, metering aerosols containing propellant and propellant-free solutions for inhalation.
- 10) Pharmaceutical composition according to claim 9, characterised in that it is an inhalable powder which contains 1 and 2 in admixture with suitable physiologically harmless adjuvants selected from among monosaccharides, disaccharides, oligo- and polysaccharides, polyalcohols, salts, or mixtures of these adjuvants with one another.
- 11) Inhalable powders according to claim 10, characterised in that the adjuvant has a maximum mean particle size of up to 250µm, preferably between 10 and 150µm.
- 12) Capsules, characterised in that they contain powders for inhalation according to claim 10 or 11.
- 13) Pharmaceutical composition according to claim 9, characterised in that it is an inhalable powder which contains only the active substances 1 and 2 as its ingredients.
- 14) Pharmaceutical composition according to claim 9, characterised in that it is an inhalable aerosol containing propellant, which contains 1 and 2 in dissolved or dispersed form.
- 15) Inhalable aerosol containing propellant according to claim 14, characterised in that it contains, as propellant gas, hydrocarbons such as n-propane, n-butane or isobutane or halohydrocarbons such as chlorinated and/or fluorinated derivatives of methane, ethane, propane, butane, cyclopropane or cyclobutane.
- 16) Inhalable aerosol containing propellant according to claim 15, characterised in that the propellant gas is TG11, TG12, TG134a, TG227 or mixtures thereof, preferably TG134a, TG227 or a mixture thereof.

- 17) Inhalable aerosol containing propellant according to claim 14, 15 or 16, characterised in that it optionally contains one or more other ingredients selected from among cosolvents, stabilisers, surfactants, antioxidants, lubricants and agents for adjusting the pH.
- 18) Inhalable aerosol containing propellant according to one of claims 14 to 17, characterised in that it may contain up to 5 % by weight of active substance 1' and/or 2'.
- 19) Pharmaceutical composition according to claim 9, characterised in that it is a propellant-free inhalable solution which contains water, ethanol or a mixture of water and ethanol as solvent.
- 20) Inhalable solution according to claim 19, characterised in that the pH of the solution is 2 - 7, preferably 2 - 5.
- 21) Inhalable solution according to claim 20, characterised in that the pH is adjusted by means of an acid selected from among hydrochloric acid, hydrobromic acid, nitric acid, sulphuric acid, ascorbic acid, citric acid, malic acid, tartaric acid, maleic acid, succinic acid, fumaric acid, acetic acid, formic acid and propionic acid or mixtures thereof.
- 22) Inhalable solution according to one of claims 19 to 21, characterised in that it optionally contains other co-solvents and/or adjuvants.
- 23) Inhalable solution according to claim 22, characterised in that it contains, as co-solvents, ingredients which contain hydroxyl groups or other polar groups, e.g. alcohols - particularly isopropylalcohol, glycols - particularly propyleneglycol, polyethyleneglycol, polypropyleneglycol, glycolether, glycerol, polyoxyethylene alcohols and polyoxyethylene fatty acid esters.
- 24) Solution for inhalation according to one of claims 22 or 23, characterised in that they contain as adjuvants surfactants, stabilisers, complexing agents, antioxidants and/or preservatives, flavourings, pharmacologically harmless salts and/or vitamins.

- 25) Solutions for inhalation according to claim 24, characterised in that they contain editic acid or a salt of editic acid, preferably sodium edetate, as complexing agent.
- 26) Solutions for inhalation according to claim 24 or 25, characterised in that they contain as antioxidants compounds selected from among ascorbic acid, vitamin A, vitamin E and tocopherols.
- 27) Solutions for inhalation according to claim 24, 25 or 26, characterised in that they contain as preservatives compounds selected from among cetylpyridinium chloride, benzalkonium chloride, benzoic acid and benzoates.
- 28) Solutions for inhalation according to one of claims 22 to 27, characterised in that they contain only benzalkonium chloride and sodium edetate in addition to the active substances 1 and 2 and the solvent.
- 29) Solutions for inhalation according to one of claims 22 to 27, characterised in that they contain only benzalkonium chloride in addition to the active substances 1 and 2 and the solvent.
- 30) Solutions for inhalation according to one of claims 19 to 29, characterised in that they are concentrates or sterile ready-to-use solutions for inhalation.
- 31) Use of an inhalable solution according to one of claims 19 to 29 for nebulising in an inhaler according to WO 91/14468 or an inhaler as described in Figures 6a and 6b of WO 97/12687.
- 32) Use of an inhalable solution according to claim 30 for nebulising in an energy-operated free-standing or portable nebuliser which produces inhalable aerosols by means of ultrasound or compressed air according to the venturi principle or other principles.
- 33) Use of a composition according to one of claims 1 to 30 for preparing a medicament for the treatment of respiratory diseases.
- 34) Use according to claim 33 for preparing a medicament for the treatment of asthma or COPD.